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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/562,261 | 07/06/2006 | Francis J. Michon | 13564-105030 | 3361 |

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| EXAMINER | |
|---|---|
| ARCHIE, NINA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 02/06/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/562,261 | MICHON, FRANCIS J. | |
| | Examiner | Art Unit | |
| | Nina A. Archie | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11/11/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4,5,7-9,11-16 and 18-30* is/are pending in the application.

4a) Of the above claim(s) *18-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-5, 7-9, 11-16, and 29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. This Office is responsive to Applicant's amendment and response filed on 10-23-08 and 11-11-08. Claims 1, 4-5, 7-9, and 12-16 are under examination. Claims 2-3, 6, 10, and 17 have been cancelled. Claims 18-28 are withdrawn. Claims 29-30 are new. Claims 1, 4-5, 7-9, 11-16, and 29-30 are presently under examination.

***Rejections Withdrawn***

2. In view of the Applicant's amendment and remark following objections are withdrawn.

a) Rejection to claims 1-2, 6-10, and 12-17 under 35 U.S.C. 102(b) is withdrawn in light of in light of applicant's amendment.

b) Rejection to claims 1-17 e rejected under 35 U.S.C. 103(a) is withdrawn in light of in light of applicant's amendment.

***New Rejection(s) and Objection(s)***

***Claim Rejections - 35 USC § and 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 4-5, 7-9, 11-16, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costantino WO 2003/007985 Date January 30, 2003 in view of Porro et al US 20060165730 (US Filing Date May 7, 2003), and Michon et al WO 2000/10599 Date March 2, 2000, and Michon et al WO 2000/10599 Date March 2, 2000.

Claims 1, 4-5, 7-9, 11-16, and 29-30 are drawn to an immunogenic conjugate comprising carrier protein, and a group Y meningococcal polysaccharide fragment obtained from and O-acetyl positive group Y meningococcal polysaccharide, wherein the group Y meningococcal polysaccharide fragment has a molecular weight less than about 150 kDa and has been O-deacetylated by at least 80%, wherein the carrier protein is covalently coupled to the group Y meningococcal polysaccharide fragment, is completely N-acetylated, wherein the immunogenic conjugate is suitable for use as a vaccine against N. meningitidis infection.

Costantino teach vaccine and immunogenic compositions comprising capsular saccharides from serogroups Y of N. meningitidis, wherein said capsular saccharides are conjugated to carrier protein (s) and/or are oligosaccharides. Constantino et al teach the material obtained (fragment) can be conjugated to a carrier protein and formulated as a vaccine (see abstract, claims). Constantino teach MenY 242975 (OAc-) and 240539 (OAc+) thus O-acetyl positive/negative group Y (see pg. 19 lines 10-15). Constantino et al teach a 30kDa cut-off membrane, and 1kDa or 3kDa cut-off membrane indicating a polysaccharide fragment that has a molecular weight less than about 150 kDa (see pg. 14 lines 1-10 and pg. 15 b and c), . Constantino et al teach carrier proteins that are bacterial toxins or toxoids, such as diphtheria or tetanus toxoids (see pg. 4 lines 15-20). Constantino et al teach a vaccine may include an adjuvant to enhance effectiveness of the composition which include, aluminum salts (alum), such as aluminum hydroxides (see claims 61-63).

Thus Constantino teach and a group Y meningococcal polysaccharide fragment obtained from and O-acetyl positive group Y meningococcal polysaccharide, wherein the group Y meningococcal polysaccharide fragment has a molecular weight less than about 150 kDa and has been O-deacetylated by at least 80%, wherein the carrier protein is covalently coupled to the group Y meningococcal polysaccharide fragment, is completely N-acetylated, wherein the immunogenic conjugate is suitable for use as a vaccine against N. meningitidis infection, wherein the group Y meningococcal polysaccharide fragment has a molecular weight from about 2.5 kDa to about 100 kDa, wherein the group Y meningococcal polysaccharide fragment has a molecular weight from about 10 kDa to about 20 kDa.

As to claims 1 and 16, to the limitation "use as a vaccine against N. meningitidis infection", "wherein the vaccine is adapted for administration by injection", said recitations are considered an intended use and thus is given no patentable weight on the conjugate. Therefore the claims are drawn to a conjugate.

Constantino is relied upon as set forth supra however, Constantino does not teach an immunogenic conjugate, and wherein the group Y meningococcal polysaccharide fragments has been O-deacetylated by at least 80%, wherein group Y meningococcal polysaccharide fragment is completely N-acetylated.

Porro et al teach that "Ps structure are conveniently represented by the O-acetyl free oxidryl residues" and that "de-O-acetylation can be selectively and quantitatively achieved therefore Porro et al anticipate the degree of de-O-acetylation is greater than 80%, for use as a vaccine against N. meningitidis infection (see [0025] and [0027]). Porro et al teach an immunogenic conjugate comprising group Y meningococcal polysaccharide covalently coupled to polymeric carrier, including O-deacetylated O-acetyl-positive group Y meningococcal polysaccharide or a fragment thereof, wherein the degree of de-O-acetylation, characterized in the degree of de-O-acetylation is 100% (see abstract, claims, see [0025] and [0027], steps 1-4). Porro et al teach a conjugate product comprising a de-O-acetylated meningococcal Y polysaccharide conjugated to a carrier protein, wherein the carrier protein is a bacterial toxin or toxoid, wherein the bacteria toxin or toxoid is tetanus ([0043]), wherein the modified meningococcal Y

polysaccharide is as defined in claim 2. Porro et al teach a vaccine, wherein the bacterial toxin or toxoid is tetanus, which comprises an adjuvant, wherein the adjuvant is aluminum hydroxide (see [0061]-[0062], which is adapted for administration by injection, wherein the conjugated material comprises a polysaccharide as defined in claim 2 (see abstract, claims).

Michon et al teach a polysaccharide-protein conjugate comprising an N-propionated polysaccharide (derived from a Meningococcus group selected from the group consisting of group Y directly conjugated to a protein such as tetanus toxoid and diphtheria toxoid at the B-position of the propionate moiety. Michon et al teach a vaccine comprising the conjugate and a method of immunizing a mammal comprising administering said vaccine. Michon et al teach a polysaccharide is de-N-acetylated by base hydrolysis using e.g. 2N NaOH, and re-N-acylated (see claims, page 6, lines 29-33; page 7, line 24 to page 8, line 10), (page 17, line 27; page 19, line 16), (page 8, line 24 to page 9, line 7). Michon et al teach that a vaccine can comprise an adjuvant such as aluminum hydroxide (see page 13. lines 15-18), and is adapted for administration by injection (see page 13, and page 25). Michon et al teach a polysaccharide-protein conjugate or oligosaccharide-protein conjugate produced by a method comprising : A) de-N-acetylating an isolated polysaccharide or oligosaccharide using a de-N-acetylating reagent to form a de-N-acetylated polysaccharide or a de-N- acetylated oligosaccharide, B) N-acryloylating the de-N-acetylated polysaccharide or the de-N-acetylated oligosaccharide with an acryloylating reagent to form an N-propionated polysaccharide or an N-propionated oligosaccharide, and C) directly conjugating the N-propionated polysaccharide or an N- propionated oligosaccharide to a protein to form the polysaccharide-protein conjugate or the oligosaccharide protein conjugate (see claim 16).

It would have been prima facie obvious at the time the invention was made to de-O-acetylate a polysaccharide as taught by Porro et al and thus make a constructional change in the conjugated polysaccharide to modify the invention with a group Y meningococcal polysaccharide conjugated to a carrier protein as taught by Constantino because Porro et al teach polyvalent formulations preferably with purified

polysaccharide antigens such as group Y meningococcal polysaccharides and glycoconjugate vaccines contribute to the immunogenicity of the whole formulation (see 0064).

It would have been prima facie obvious at the time the invention was made to completely N-acetylate a polysaccharide as taught by Michon et al and thus make a constructional change in the conjugated polysaccharide to modify the invention with a polysaccharide conjugated to a carrier protein as taught by Constantino because both Constantino and Michon et al both teach polysaccharide-protein conjugate or oligosaccharide-protein conjugate derived from group Y (see claims).

***Status of the Claims***

4. No claims are allowed.

Claims 1, 4-5, 7-9, 11-16, and 29-30 are rejected.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie
Examiner
Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645